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510(k) Summary of Safety and Effectiveness

JAN 0 3 2013

510(k) Summary As required by 21 CFR 807.92: K123363

Name of Sponsor: Metric Medical Devices, Inc., 846 Silver Springs, Helotes, TX, 78023

Contact: W. Casey Fox, Ph.D., P.E., President

Date Prepared: 1/2/2013

Proprietary Name: The Super Staple™ Classic

Classification Name: Staple, Fixation, Bone

Device classification: Class II per 21 CFR 888.3030

Product Device Code: JDR

Substantial Equivalence: The Super Staple™ is substantially equivalent to the Memory™ Staple (Depuy), Memory Staple™ (BioPro, Inc.) EasyClip™ (Memometal Inc.), and OSStaple™ (BioMedical Enterprises, Inc.) in terms of intended use and indications for use, material, design and function. Any minor differences between these devices or their performance do not raise any questions of safety and effectiveness.

Intended Use: The Super™ Staple is intended for 1) hand and foot bone fragment and osteotomy fixation and joint arthrodesis, 2) fixation of proximal tibial metaphysis osteotomy and 3) adjunctive fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bones such as the pelvis, scapula and sternum.

Performance Data: Corrosion testing per ASTM F2129 "Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices" was performed. The corrosion behavior of the Super Staple™ was acceptable for all samples tested and substantially equivalent to the predicate devices.

Staple Compression, pull-out, ultimate strength and fatigue strength were measured for the Super Staple™ and predicate devices. Compression tests showed that the Super Staple™ has a substantially equivalent compression force when compared to the predicate staples tested.

Pull-out tests showed that the Super Staple™ had a substantially equivalent pull-out force when compared to the predicate staples tested. In this test the performance of the Super Staple™ meets the performance of the predicate devices.

Strength of the Super Staple™ in failure load, stiffness and deflection was measured and found substantially equivalent to the predicate device tested. Fatigue testing S-N curves and their characteristic equations showed that the Super Staple™ withstands substantially equivalent load at run-out when compared to the tested predicate device. Thus the fatigue performance of the Super Staple™ is substantially equivalent or better than the predicate devices.

Device Description: The Super Staple™ is a two leg U-shaped staples fabricated from nitinol alloy with an S-shaped bridge design. These U-shaped compressive staples range in width from 9 to 30 millimeters. Staple prong length ranges from 7 to 30 mm and staples have prongs of equal and unequal length.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 3, 2013

Metric Medical Devices, Incorporated
% W. Casey Fox, Ph.D.,PE
President
846 Silver Springs
Helotes, Texas 78023

Re: K123363
Trade/Device Name: Super Staple™ Classic
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: October 30, 2012
Received: November 1, 2012

Dear Dr. Fox:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

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510(k) Number (if Known): K123363

Device Name: Super Staple™ *Classic*

Indications for use:

The Super™ Staple is intended for 1) hand and foot bone fragment and osteotomy fixation and joint arthrodesis, 2) fixation of proximal tibial metaphysis osteotomy and 3) adjunctive fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bones such as the pelvis, scapula and sternum.

Prescription Use X (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices 2013.01.03 12:59:25 -05'00'